UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748** **MDL 2545** **JUDGE MATTHEW F. KENNELLY** **This Document Relates to:** ***Mitchell* v. *AbbVie*,** **Case No. 1:14-cv-09178**

DEFENDANTS' MOTION AND SUPPORTING MEMORANDUM
TO EXCLUDE CUMULATIVE EXPERT TESTIMONY

The Court should exclude Dr. Pence's testimony as cumulative under Federal Rule of Evidence 403. Her testimony is redundant of, and consistently overlaps with, the testimony offered by several other witnesses called by Plaintiff, including Dr. Kessler, Dr. Ardehali, Mr. Wojtanowski, and Mr. Miller.[1]

Dr. Pence offers two general opinions, both of which are cumulative with testimony from Plaintiff's other witnesses. *First*, Dr. Pence opines that AbbVie did not adequately test AndroGel for cardiovascular (CV) risk. *See Konrad II* Trial Tr. 2362:20–2363:5, attached hereto as Exhibit A. This testimony recapitulates that of Dr. Ardehali, Dr. Kessler, Mr. Wojtanowski, and Mr. Miller. *See* Ex. A at 1399:20–22 (Dr. Ardehali: "Q. That [kind of randomized clinical trial] hadn't been done by AbbVie by that point in time? A. That's correct."); *id.* at 748:7–22 (Dr. Kessler: "[W]hat it's basically saying is not enough safety and efficacy done—actually, it's talking about safety particularly here . . . because FDA is saying . . . you will need to further support the long-term safety of your product in the indicated population . . . especially in regard to issues, long-term prostate and cardiac health."); *id.* at 342:8–13 (Mr. Wojtanowski: "Q. [The Food and Drug Administration (FDA)] shared concerns about cardiovascular safety of your drug, right? A. Yes. Q. Because your cardiovascular safety had not been studied, right? A. Not specifically, yes."); *id.* at 1095:14–17 (Mr. Miller: "Q. So in the seven years that you said you needed more study, you never once started that cardio—6,000-person cardiovascular outcome study that you said was necessary, true? A. True.").

Second, Dr. Pence opines that AbbVie did not adequately warn of CV risk. *See* Ex. A at 2362:4–11. This testimony reiterates that of Dr. Ardehali, Mr. Wojtanowski, and Mr. Miller. *See* Ex. A at 1402:14–17 (Dr. Ardehali: "If I was consulting a company, I would have told them at that point [in 2007] there is enough here that something should be done. Patients should be

[1] This memorandum provides significant examples of this overlap but is not intended to be exhaustive.

warned. Physicians should be warned."); *id.* at 428:22–429:1 (Mr. Wojtanowski: "[Q. D]uring this period of time from 2000 to 2010, the period of time before Mr. Konrad had his heart attack, was there a heart attack warning in the label for AndroGel? A. No."); *id.* at 1051:13–17 (Mr. Miller: "Q. And, in fact, until the FDA implemented the advice from the advisory committee, there was never any risk for—there was never any warning as to the heart attack risk in the AndroGel label, true? A. Again, for heart attack, no.").

Moreover, Dr. Pence supports her two general opinions with specific testimony that largely repeats testimony from other Plaintiff witnesses on more discrete subjects. *First*, both Drs. Pence and Kessler testify in detail about the FDA's drug approval process. They both explain that a drug manufacturer must conduct "adequate and well-controlled" trials before marketing a drug, that the trials must produce "substantial evidence" of safety and effectiveness for the specific indication sought, that the manufacturer must submit first an Investigational New Drug application (IND) and then a New Drug Application (NDA), that the manufacturer bears primary responsibility for monitoring safety, that it must continue to monitor safety even after approval, that the manufacturer must warn of newly identified risks, that it can do so through the label, and that the manufacturer may go through the Change Being Effected (CBE) process to update the label without prior FDA approval. *See* Ex. A at 2358:4–19, 2363:17–2373:14, 2383:14–20; *id.* at 705:13–708:13, 710:25–712:23, 753:11–21.

Second, Dr. Pence, Dr. Kessler, Dr. Ardehali, Mr. Wojtanowski, and Mr. Miller all describe purported deficiencies in AbbVie's clinical trials for purposes of determining CV risk. In particular, they discuss criticisms of AbbVie's 017 preapproval study and 035 extension study on the various overlapping grounds that the studies did not have a placebo control group, were not blinded, relied on pharmacokinetic data, lacked sufficient power, and included signs of

potential CV risk. *See* Ex. A at 2383:21–2397:19; *id.* at 724:1–16, 738:10–740:6, 751:6–752:23; *id.* at 1349:2–1352:8, *id.* at 304:13–307:5, 319:14–322:10; *id.* at 1013:3–1014:7.

Third, Dr. Pence, Dr. Ardehali, Mr. Wojtanowski, and Mr. Miller all provide testimony concerning whether AbbVie should have, but did not, conduct a large-scale CV outcomes study. *See* Ex. A at 2402:8–2403:23, 2411:12–17; *id.* at 1399:5–22; 1429:18–23; *id.* at 295:7–21, 328:8–11, 342:8–343:3; *id.* at 1020:12–1021:1, 1041:14–1042:17, 1044:2–16.

Fourth, Dr. Pence, Dr. Kessler, and Mr. Wojtanowski all testify about the alleged insufficiency of the testing to establish AndroGel as an effective treatment for age-related hypogonadism, as well as various related symptoms and conditions, such as erectile dysfunction, fatigue, decreased sexual desire, worsened mood, and obesity-related hypogonadism. *See* Ex. A at 2401:2–2402:3; *id.* at 747:19–748:22, 750:10–751:2, 752:24–753:10; *id.* at 323:11–327:2.

Fifth, the same three witnesses testify that AbbVie could only market AndroGel for indicated conditions and therefore could not promote it as a treatment for age-related hypogonadism. *See* Ex. A at 2366:3–2367:2, 2403:25–2404:16; *id.* at 708:14–709:14, 715:24–716:7, 744:21–746:6, 766:1–11; *id.* at 299:3–301:1, 318:9–13.

Sixth, Drs. Pence and Ardehali both testify that reasonable evidence of causal association between AndroGel and CV risk existed by 2007 such that AbbVie should have warned patients and doctors about such a risk at that time. *See* Ex. A at 2362:12–17, 2404:17–2406:19, 2411:6–2411:11; *id.* at 1302:6–8; 1402:4–19.

Finally, Dr. Pence, Mr. Wojtanowski, Mr. Miller, and Dr. Kessler all testify about the actions that the FDA took in 2015, identifying potential CV risk, changing the label, and directing AbbVie to conduct further testing. *See* Ex. A at 2409:21–2411:5; *id.* at 282:4–292:16; *id.* at 1016:6–1017:1, 1020:3–1021:5; *id.* at 742:21–743:10.

Given the significant overlap between Dr. Pence's testimony and that of the other witnesses called by Plaintiff, the Court should exclude her testimony as cumulative.

Dated: March 8, 2018

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CERTIFICATE OF SERVICE

I, David Bernick, hereby certify that on March 8, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ David Bernick
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